Oxford Cambridge and RSA

OCR-set Assignment

Sample Assessment Material

OCR Level 3 Alternative Academic Qualification Cambridge Advanced National in Human Biology

Unit F177: Drug development

Scenario Title: Developing a drug for Progress Health

Valid for assessment from September 20XX to 20XX.
For use by students beginning the qualification in September 20XX.

This is a sample OCR-set assignment which should only be used for practice**.**

This assignment **must not** be used for live assessment of students.

The live assignments will be available on our secure website, 'Teach Cambridge'.

The OCR administrative codes linked to this unit are:

- unit entry code F177
- certification code H149

The regulated qualification number linked to this unit is:

610/3946/9

Duration

About:

- 15 hours of supervised time (GLH)
  (work that **must** be completed under teacher supervised conditions)
- 10 hours of unsupervised time
  (work that students can complete independently without teacher supervision)

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Information and instructions for Teachers

Using this assignment

This assignment provides a scenario and set of related tasks that reflects the development of a new drug.

You can give this to students on or after 1 June 202X to help them understand it before they start using it for assessment. The dates for which students can use it for assessment are shown on the front cover.

The assignment:
- Is written so that students have the opportunity to meet the requirements of all assessment criteria for the unit.
- Will tell students if their evidence must be in a specific format. If the task does not specify a format, students can choose the format to use.
- **Must** be completed under teacher supervision. Any unsupervised time allowed will be stated below and explained in the assessment guidance.

We have estimated that this assignment will take about 15 hours of supervised time and 10 hours of unsupervised time to complete. Students should need approximately:
- 5 hours to complete Task 1
- 9 hours to complete Task 2
- 5 hours to complete Task 3
- 6 hours to complete Task 4

You **must**:

- Use an OCR-set assignment for summative assessment of students.
- Familiarise yourself with the assessment criteria and assessment guidance for the tasks. These are given at the end of each student task. They are also with the unit content in **Section 5** of the Specification.
  Assessment guidance is only given where additional information is needed. There might not be assessment guidance for each criterion.
- Make sure students understand that the assessment criteria and assessment guidance tell them in detail what they need to do in each task.
- Read and understand **all** the rules and guidance in **Section 7** of the Specification **before** your students start the set assignments.
- Make sure that your students complete the tasks and that you assess the tasks fully in line with the rules and guidance in **Section 7** of the Specification.

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- Give your students the Human Biology **Student guide to NEA assignments before** they start the assignments.
- Complete the **Teacher Observation Record** for **Task 3**. You **must** follow the guidance given when completing it.

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You **must not**:

- Use live OCR-set assignments for practice or formative assessment. This sample assessment material **can** be used for practice or formative assessment.
- Use this sample assessment material for live assessment of students.
- Allow group work for **any** task in this assignment.
- Change any part of the OCR-set assignments or assessment criteria.

Pages 1-4 are for teachers only. Please do **not** give **Pages 1-4** to your students.

You can give **any** or **all** of the pages **that follow** to your students.

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Tasks for students and assessment criteria

Unit F177: Drug development

Scenario Title: Developing a drug for Progress Health

Valid for assessment from September 20XX to 20XX.
For use by students beginning the qualification in September 20XX.

Scenario

You are part of a drug development team who have been given the chance to pitch a new drug within the area of antimicrobials to treat infection. The drug has been through pre-clinical research and is ready for clinical trials.

Funding has become available for the clinical trials stage of this drug development from Progress Health. Progress Health have declared that applications must include a written proposal and pitched presentation. The pitched presentation will need to be performed to three panel members from Progress Health. The panel includes:

- Chief Scientific Officer
- Chief Financial Officer
- A lawyer focusing on legal and ethical affairs.

You have been asked to lead on the research and production of the written proposal and presentation. You will also deliver the presentation to the rest of your drug development team as part of the preparation.

The features of the drug include:

- Antimicrobial
- Treat ear infections caused by bacteria or fungus
- Pre-clinical research currently suggests this drug should be administered as a liquid
- The suggested strength is 25 mg per 100 ml
- The suggested dosage is currently two drops
- Free of colouring agents
- No smell
- In animal trials:
  - the drug was generally administered twice a day
  - symptoms were alleviated after approximately 7 days of use of the drug
  - all signs of infection (checked with a swab) were gone between 10 and 14 days.
- Side-effects seen in animal trials include:
  - with a high dosage skin irritation where liquid was applied
  - in a very few cases, with a high dose, skin irritation developed into sores
  - a very few cases of loss of appetite
  - no dizziness observed

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- no deaths were caused by the administration of this drug.

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Task 1

Researching the market for the new drug

Topic Areas 1, 2 and 3 are assessed in this task.

The task is:

Research other drugs available and the potential market of the new drug.

- Before you can create your drug development proposal, you need to research the other drugs available and the potential market of the new antimicrobial drug to treat infections.

Your evidence **must** include:

- Written evidence.

Use the assessment criteria below to tell you what you need to do in more detail.

Pass	Merit	Distinction
P1: Use research to **compare** the properties of other drugs with a similar aim to the new drug being developed. (PO4)	**M1: Explain** how the properties of the new drug will affect the development process. (PO2)	
P2: Use research to **describe** the effects of other drugs with a similar aim as the new drug being developed. (PO4)	**M2:** Use research to **summarise** the different market factors which may impact on the development of the new drug. (PO4)	
P3: Use research to **explain three** ways that specific legislation will affect the development of the new drug being developed. (PO4)		

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Assessment Guidance

This assessment guidance gives you information to meet the assessment criteria. There might not be additional assessment guidance for each criterion. It is only given where it is needed. You must read this guidance before you complete your evidence.

Assessment Criteria	Assessment guidance
Task 1	• The research element of the criteria in this Task does **not** need to be completed under teacher supervised conditions but is necessary in order for students to access the criteria.
P1	• Students must research the properties of other drugs with a similar aim to the new drug being developed. • 'Other drugs with a similar aim' might be, for example, other drugs to treat infections (could be to treat a different area of the body than given in the scenario) or the type of drug (e.g. antimicrobial drugs, antibacterial, antifungal, anti-inflammatory, antiviral). • 'Properties' means different features such as dosage, resistance, routes of administration, strength. • Students must use their research to compare the properties of other drugs with the new drug being developed.
P2	• The competitor drugs focused on in **P2** must be the drugs compared to the new drug in **P1**. • Students must describe the effects of similar drugs on the market - including side-effects.
P3	• Students must use research to explain **three** ways that specific legislation will affect the development of the new drug being developed. • The three different ways could come from one or multiple pieces of legislation.

Advice:

- Remember to clearly reference any information used from books, websites or other sources to support your evidence.

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Task 2

Creating a written proposal for the drug development

Topic Areas 1, 2 and 3 are assessed in this task.

The task is:

Create a proposal for the development of the new drug.

- Having established the place of the drug in the market, you now need to produce a written proposal building on your understanding of the drug and market from **Task 1** and applying your knowledge and understanding of the drug development process.

Your evidence **must** include:

- A written proposal for the development of the drug
- Written evidence.

Use the assessment criteria below to tell you what you need to do in more detail.

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td>P4: Create a written proposal describing the clinical trial phases of the development of the new drug.
(PO4)</td><td rowspan="3">M3: Explain the chosen participation groups in each phase of the clinical trials in terms of their validity and reliability.
(PO2)</td><td>D1: Justify the decisions made in the written proposal with scientific rationale.
(PO3)</td></tr>
<tr><td>P5: Explain how it can be determined whether the suggested dosage is safe and effective during the development of the new drug.
(PO2)</td><td rowspan="2">D2: Evaluate the risk of side effects beyond those identified in pre-clinical trials for the new drug.
(PO3)</td></tr>
<tr><td>P6: Explain how the properties of the new drug influence the purpose of each phase of the clinical trial.
(PO2)</td></tr>
<tr><td>P7: Explain the roles of the various stakeholders involved in the development of the new drug.
(PO2)</td><td>M4: Discuss potential success criteria for the various stakeholders of the new drug.
(PO3)</td><td>D3: Assess the ethical considerations of the development of the new drug.
(PO3)</td></tr>
</table>

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Assessment Guidance

This assessment guidance gives you information to meet the assessment criteria. There might not be additional assessment guidance for each criterion. It is only given where it is needed. You must read this guidance before you complete your evidence.

Assessment Criteria	Assessment guidance
P4	• The written proposal must cover the clinical trial phases of clinical research, regulatory approval and post market surveillance.
P5	• Students must focus on the specific features of the new drug in the case study to explain how to determine that the suggested dosage given is safe and would fulfil the aim whilst limiting the side-effects given. • Students can use their research from **Task 1**.
M4	• **M4** is an extension of **P7.**
D1	• Students must justify the decisions made in the written proposal using scientific rationale. • Students will use their understanding of the unit content to provide valid reasons for the decisions made.

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Task 3

Refining your pitch

Topic Areas 1, 2, 3 and 4 are assessed in this task.

The task is:

Create a 5-minute presentation to pitch your proposal from **Task 2**.

Deliver your practice presentation.

- As part of the process, proposals need to be presented to the panel from Progress Health who decide on which proposals will receive funding.
- The internal process with your team involves a practice presentation based on the written proposal.
- You will create and deliver this presentation to members of your drug development team as part of the preparation of your proposal.

Your evidence **must** include:

- A presentation in a suitable format and any accompanying notes and materials
- A Teacher Observation Record Form for the presentation
- Written evidence.

Use the assessment criteria below to tell you what you need to do in more detail.

Pass	Merit	Distinction
P8: Create an appropriate presentation which summarises the drug development proposal. (PO4)	**M5: Explain** how the presentation has been tailored to all of the different members of the panel. (PO2)	**D4: Justify** the inclusion and omission of content from the written proposal in the presentation using scientific reasoning. (PO3)
P9: Deliver the presentation to the intended audience, with explanations of rationale beyond what is included in the presentation documentation. (PO4)		

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Assessment Guidance

This assessment guidance gives you information to meet the assessment criteria. There might not be additional assessment guidance for each criterion. It is only given where it is needed. You must read this guidance before you complete your evidence.

Assessment Criteria	Assessment guidance
Task 3	• Presentations will need to be aimed at a length of 5 minutes, but flexibility should be allowed. • Students can either deliver the presentation to the teacher, peers or a combination of both. If the presentation is delivered to peers only, this must be recorded, so that the teacher can use the recording to complete the Teacher Observation Record for **P9** (you do **not** need to submit this for moderation). • The focus of other members of the drug development team is from the scenario. There is no requirement for the presentation to take place in front of a certain number of other students. • Students can create their presentation in the format they feel is most appropriate. This could include a poster, a PowerPoint presentation, a flow diagram, etc.
P9	• Teachers must complete a Teacher Observation Record for each student to evidence they have met the criteria. Students must also read and sign it. • The Teacher Observation Record form should describe in detail how the student delivered the presentation to the intended audience, with explanations of rationale beyond what is included in the presentation documentation. • The intended audience is the panel members given in the scenario.
D4	• Students must apply knowledge and understanding from the unit content learnt to give valid reasons for the inclusion or omission of content from the written proposal in their presentation. This will form their justification.

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Task 4

Reviewing your proposal and presentation

Topic Areas 1, 2, 3 and 4 are assessed in this task.

The task is:

Review your proposal from **Task 2** and presentation from **Task 3**.

- For the review you need to reflect on your proposal and presentation.
- You must also obtain feedback from peers on the presentation. Feedback received about the presentation is used as part of a review process to finalise the proposal ready for submission.

Your evidence **must** include:

- Written evidence.

Use the assessment criteria below to tell you what you need to do in more detail.

Pass	Merit	Distinction
P10: Summarise the feedback received for your presentation. (PO2)	**M6: Discuss** the strengths and weaknesses of your drug development proposal. (PO3)	**D5: Assess** how your drug development proposal could be improved to provide the greatest chance of success of receiving funding. (PO3)
P11: Analyse how the presentation of your pitch could be improved. (PO3)		
P12: Explain how **three** other pieces of information would have been useful when creating the drug development proposal. (PO2)	**M7: Evaluate** how the information suggested in **P12** might have affected the proposal. (PO3)	

Assessment Guidance

This assessment guidance gives you information to meet the assessment criteria. There might not be additional assessment guidance for each criterion. It is only given where it is needed. You must read this guidance before you complete your evidence.

Assessment Criteria	Assessment guidance
P10	• Students must clearly express the most important points stemming from the feedback received for their presentation in a short and clear form.

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	• The feedback for the presentation might be provided by the teacher and/or other students.
M7	• **M7** is an extension of **P12**.

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Teacher Observation Record Form

Use this form to record what is observed.
Read the **guidance notes** below the form **before** you complete the form.

OCR Level 3 Alternative Academic Qualification Cambridge Advanced National in Human Biology (Extended Certificate)

Unit number:	F177
Unit title:	Drug development
Task number:	3
Task title:	Refining your pitch

Student's name:	
Date the activity was completed:	

What extra evidence is attached to the form?	

The **teacher** fills in this section:

This activity relates to Assessment Criterion **P9**. You **must** describe in detail how the student delivered the presentation to the intended audience, with explanations of rationale beyond what is included in the presentation documentation.	
How does the activity meet the requirements of the Assessment Criteria? You **must** describe: 1. what the student did 2. how it relates to the relevant Assessment Criteria.	
Teacher's name:	
Teacher's signature:	
Date:	

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The **student** fills in this section:

I agree with my teacher's description of how I completed this activity Yes ☐	
Use this space to make any extra comments.	
Student's signature:	
Date:	

Guidance notes

Both the teacher **and** the student are responsible for completing this form.

The **teacher must**:
- use the form to describe in detail what they observed the student doing.
- give contextualised details of what the student did and how this relates to the Assessment Criteria.
- say how well the activity was completed in relation to the Assessment Criteria with reasons.
- share what they have written with the student and offer the opportunity to discuss if the student disagrees with what is written.
- reach agreement with the student before the work is submitted for moderation.
- sign and date the form as evidence of agreement.

The **student must**:
- reach agreement with the teacher before the work is submitted for moderation.
- use the form to show that they agree with the teacher's record of the activity observed.
- sign and date the form as evidence of agreement.

The form **must**:
- be accompanied by extra evidence, as required by the task.
- provide evidence that is individual to the student.

The form **must not**:
- contain a simple repeat of the Assessment Criteria.
- contain just a list of skills.
- be completed by anyone other than the teacher observing the activity and the student completing the activity.
- be written by the student for the teacher to sign.
- be used to evidence achievement of a whole unit or task in isolation.

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NEA Command Words

The table below shows the command words that may be used in the NEA assignments and/or assessment criteria.

Command Word	Meaning
Adapt	• Change to make suitable for a new use or purpose
Analyse	• Separate or break down information into parts and identify their characteristics or elements • Explain the different elements of a topic or argument and make reasoned comments • Explain the impacts of actions using a logical chain of reasoning
Assess	• Offer a reasoned judgement of the standard or quality of situations or skills. The reasoned judgement is informed by relevant facts
Calculate	• Work out the numerical value. Show your working unless otherwise stated
Classify	• Arrange in categories according to shared qualities or characteristics
Compare	• Give an account of the similarities and differences between two or more items, situations or actions
Conclude	• Judge or decide something
Describe	• Give an account that includes the relevant characteristics, qualities or events
Discuss (how/whether/etc)	• Present, analyse and evaluate relevant points (for example, for/against an argument) to make a reasoned judgement
Evaluate	• Make a reasoned qualitative judgement considering different factors and using available knowledge/experience
Examine	• To look at, inspect, or scrutinise carefully, or in detail
Explain	• Give reasons for and/or causes of something • Make something clear by describing and/or giving information
Interpret	• Translate information into recognisable form • Convey one's understanding to others, e.g. in a performance
Investigate	• Inquire into (a situation or problem)
Justify	• Give valid reasons for offering an opinion or reaching a conclusion
Research	• Do detailed study in order to discover (new) information or reach a (new) understanding
Summarise	• Express the most important facts or ideas about something in a short and clear form

We might also use other command words but these will be:

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- commonly used words whose meaning will be made clear from the context in which they are used
- subject specific words drawn from the unit content.

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